REMARKS

Upon entry of this amendment, claims 1, 3, 5-16, 36-51, and 60-61 are pending. Claim 1 is amended; the amendment is supported in the specification, for example, at paragraph [0016] and Table 2 on page 15. Other claims are amended to make them consistent with the amendments to claim 1. These amendments are made for the purposes of advancing prosecution and narrowing the issues on appeal. Applicants reserve the right to present the original claims in a continuation application.

35 U.S.C. § 102/103 Rejection

Reconsideration is requested of the rejection of claims 1, 12-16, 36-38, 41, 42, 44, 60, and 61 as anticipated by or alternatively unpatentable over EP 0349453 (Martani) under 35 U.S.C. § 102/103. Claim 1 is directed to a method of removing sodium from an animal subject comprising administering to an animal subject in need thereof an effective amount of a non-absorbed sodium-binding composition comprising a sodium-binding polymer. The polymer comprises particular cation exchange moieties and has an *in vivo* sodium binding capacity of 4 mmol or more per gram of said polymer in a human calculated by measuring the amount of sodium in the feces after administration of the sodium-binding polymer to a human patient. This composition is administered to an animal subject suffering from hypertension, chronic heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload.

Martani discloses compositions for the prolonged release of various cationic or anionic active ingredients. The cationic active ingredients are loaded on various anionic resins, particularly, polystyrene sufonate resin and then the polystyrene sufonate-active ingredient complex is coated with either an anionic (e.g., Eudragit® S) or preferably, a cationic (e.g., Eudragit® RL) polymer coating to delay the release of the active ingredient once administered. For anionic active ingredients, a cationic resin such as cholestyramine is used to complex the active ingredient and an anionic polymer coating (e.g., Eudragit® S) is used to coat the cholestyramine-active ingredient complex.

In contrast, claim 1 requires administration of a sodium-binding polymer polymer comprising particular cation exchange moieties that has an *in vivo* sodium binding capacity of 4

mmol or more per gram of said polymer in a human. Martani does not anticipate this claim element because polystyrene sulfonate is not specified by claim 1 and the literature shows that polystyrene sulfonate has an *in vivo* sodium binding capacity of from about 0.4-1.2 meq[1]/gram polymer.[2]

Further, the specific cation exchange moieties specified by claim 1 and the *in vivo* sodium binding capacity of 4 mmol or more per gram of said polymer would not have been obvious from the Martani disclosure. Martani is concerned with controlled release of various ionic active ingredients. For this purpose, polystyrene sulfonate is exemplified, but Martani provides no disclosure that would have led a person of ordinary skill to select the particular cation exchange polymers required by claim 1 from the universe of possible cation exchange polymers. Moreover, the weight of the literature shows that polystyrene sulfonate has an *in vivo* sodium binding capacity of from about 0.4-1.2 meq/gram polymer and there is no disclosure in Martani that would have led a person of ordinary skill to have suspected that the Martani compositions would have a higher sodium binding capacity. Thus, claims 1, 12-16, 36-38, 41, 42, 44, 60, and 61 are patentable over EP 0349453 (Martani) under 35 U.S.C. § 102 or 103.

Provisional Double Patenting Rejection

Reconsideration is requested of the provisional rejection of claims 1, 12, and 36-44 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 30, 31, 40, and 45 of copending Application No. 10/965,274 and the provisional rejection of claims 1, 12-14, 36-43, 60, 61 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 43-49, 52-59, and 61-64 of copending Application No. 11/096,209. It is noted that these rejections are provisional and upon issuance of patents, applicant will consider filing a terminal disclaimer to obviate this basis for rejection when the application is otherwise in condition for allowance.

[1] Since sodium is a monovalent ion, mmol/gram and meq/gram are equivalent.
[2] McChesney et al., "Some aspects of cation exchange resins as therapeutic agents for sodium removal," Ann N Y Acad Sci., 57(3):252-259 (1953); Reference No. 41 on IDS form submitted on October 21, 2005.

Rejoinder

Pursuant to MPEP §821.04, Applicants again request rejoinder of withdrawn claims 3, 5-11, 45-48, and 50-51 as they depend from claim 1, require all of the limitations of claim 1, and claim 1 is amended to include specific acid resin polymers. Furthermore, applicants submit that these claims are allowable over the references relied upon by the Office.

Other References

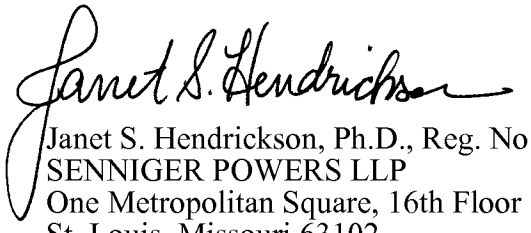
Emerson et al.(Ann N Y Acad Sci., 57(3):280-290 (1953); submitted in a 1449/PTO form as Reference No. 26 on October 21, 2005) disclose the use of polystyrene sulfonate and polyacrylic acid cation exchange polymers to remove cations from humans. Although Emerson et al. disclose that the polyacrylic acid cation exchange polymer demonstrated a capacity of 5 meq/gram of polymer, neither polystyrene sulfonate or polyacrylic acid are among the cation exchange polymers specified by claim 1.

CONCLUSION

Applicant submits that the present application is in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,



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